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NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES

diabetes NEWSLETTER

University of Medicine and Dentistry of New Jersey ■ Published by UMDNJ-Center for Continuing Education in the Health Professions

UMD NEW JERSEY

stratified treatment guidelines

FOR THE ELDERLY PATIENT WITH DIABETES

Those seniors whose general medical condition and statistics indicate greater than a 10-year life expectancy should be treated by the usual adult guidelines which do not put them at undue risk of hypoglycemia.

Table of Contents

author disclosure of commercial support

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How aggressively would you treat an overweight asymptomatic 75 year old woman found to have a fasting serum glucose of 275 mg/dl? The experienced physician knows instinctively that there is never one easy answer when dealing with a human being. The answer depends on the patient's cognitive function — likely to predict her compliance with recommendations, her motivation, her risk of falling, her quality of life, and ultimately her prognosis.

The American Diabetes Association (ADA) updates its practice recommendations for the care of diabetic patients every January, basing its conclusions on continued analysis of the Diabetes Control and Complications Trial (DCCT) and other clinical outcome data. The DCCT, the landmark of all diabetes treatment trials, demonstrated that tight control of type 1 diabetes prevented microvascular complications — in the eye, kidney and peripheral nervous system. In 1998, the ADA recommended that the fasting and preprandial blood glucose in diabetic patients be maintained at 120 mg/dl or less. The recommendation is unqualified — saying nothing about the age of the patient! Values of the hemoglobin A_{1C} of 8% or more are considered action levels requiring more aggressive therapy. These tight recommendations represent expert consensus. Most experts believe that the auspicious outcome of the DCCT, though realized in a cohort of young type 1 patients, could be expected in the entire universe of diabetic patients who achieve glycemic goals. Ninety percent of that universe consists of type 2 diabetic patients. Advancing life expectancy is resulting in the diagnosis of many patients with type 2 diabetes after age 70. Does the outcome data derived from the DCCT apply to this rapidly growing group of diabetic patients?

The recently published results of the United Kingdom Prospective Diabetes Study, the largest study on type 2 diabetes ever conducted, have shown that tight blood glucose control reduces diabetic complications in blood vessels, nerves, eyes, and kidneys. There was a very strong trend demonstrating the effects of tight treatment on reducing myocardial infarctions, but there was no effect on cerebral vascular accidents. →

Table 1a

GERIATRIC DIABETES PERFORMANCE MEASURES

(Age > or = 65 years of age; Life Expectancy <10 years)*

FREQUENCY OF VISITS....if meeting goals: every 6 months
....if not meeting goals: every 3 months, or as indicated

WEIGHT & REVIEW OF ALL MEDICATIONS....every visit: compliance issues and risks of drug interactions

CARDIOVASCULAR ASSESSMENT....BP every visit; EKG in adults, baseline and prn

COGNITIVE AND FUNCTIONAL ASSESSMENT....yearly

FEET EXAMINATION....check every routine visit (two to four times/year) to include vascular and neuro check

EYE EXAMINATION....dilated eye exam yearly

LIPID PROFILE....with initial diagnosis and yearly if abnormal, every 5 years if normal

HEMOGLOBIN A_{1c}....if meeting goals: yearly, or as indicated if not meeting goals: every 3 months

FASTING OR RANDOM BLOOD GLUCOSE....every diabetic visit

CREATININE....yearly

U/A FOR PROTEINURIA ACCORDING TO GOALS....yearly

FLU VACCINE....yearly

PNEUMOVAX....offered every 5 years

In preparation for this essay, three highly respected geriatricians in New Jersey were asked what glucose values indicate optimal diabetes management of their patients. In essence, all said that there were no data and that each patient should be managed individually based on clinical judgment. If you have ever tried to develop a disease management guideline, you realize that clinical judgment is a difficult concept to delineate in a schematic outline.

The New Jersey Diabetes Council has been evaluating what constitutes optimal care of diabetic patients in New Jersey over the last three years. This Council consists of representatives from the New Jersey Department of Health and Senior Services, Managed-Care Organizations, Federally Qualified Health Centers, Peer Review Organization, medical insurance industry, and diabetes educators, nutritionists and physicians The Council considers the economic impact of every medical practice issue in the care of diabetic patients. For instance, a recommendation that an EKG be part of the medical record of every patient independent of age and other risk factors could cost a health clinic or HMO which adopts the recommendation over $100,000 per year. Similar issues involve how often a diabetic patient should have a dilated fundoscopic examination or what factors indicate that the foot be examined on every visit.

When considering the glycemic goals of elderly patients with diabetes mellitus, the New Jersey Diabetes Council learned that the Veterans Administration Health System was also grappling with the same difficulties in its aged patient population. Leonard Pogach, MD, Chief of Endocrinology at the East Orange VA Health System, has become a national leader in developing guidelines for the care of diabetic patients. A committee consisting of thought leaders in the VA, academic and clinical medicine, and the public health sector has proposed a set of guidelines that are evidence based. An

Table 1b

REFERRALS TO SPECIALISTS AS NEEDED

NUTRITIONAL COUNSELING: REGISTERED DIETICIAN ..... at diagnosis and evaluate as needed

FAMILY AND SELF-MANAGEMENT EDUCATION: RN, CDE ..... at diagnosis and evaluate yearly

HYPER/HYPOGLYCEMIC SYMPTOMS OR RISKS: DIABETOLOGIST ..... Fasting/preprandial/bedtime blood sugar consistently not meeting goals $HbA_{1C} \geq 9\%$

RETINOPATHY: OPHTHALMOLOGIST/ RETINAL SPECIALIST ..... Yearly or Acute exacerbation

FOOT DEFORMITIES, NEUROTROPIC ULCERS: PODIATRIST, ORTHOPEDIC OR VASCULAR SURGEON ..... Acute exacerbation

*If life expectancy is greater than 10 years, the results of the Diabetes Control and Complications Trial indicate that good control will prevent microvascular and neurological complications. Therefore, a geriatric patient with a greater than 10 year life expectancy should be treated according to the Adult Performance Measures.

references

1. Diabetes Control and Complications Record Group. The effects of intensive treatment of diabetes on the development and progression of long-term complications of insulin dependent diabetes mellitus., N. Engl J. Med (1993) 329:977.
2. Laslo R. D. the DCCT: Implications for policy and practice (editorial), N. Engl J. Med (1993) 329:1035.
3. American Diabtetes Association. Clinical practice recommendations 1999. Diabetes Care, Supplement 1 (1999) 22.
4. American Diabtetes Association. Report of the expert committee on the diagnosis and classification of diabetes mellitus, Diabetes Care (July 1997) 20:1183-1197.

example of evidence-based research, the DCCT spanned a time frame of 10 years. The data concluded that reductions in hemoglobin A_{1C} will directly reduce the occurrence of microvascular complications in diabetes. If an elderly diabetic patient has a life expectancy of less than 10 years, will optimal glucose management designed to prevent microangiopathy have a more favorable impact on patient quality of life than efforts to keep the patient free of symptoms of hyper- or hypoglycemia? There is no outcome data to match this clinical circumstance. The VA guideline indicates that the patient's diabetes mellitus should be maintained without such symptoms.

The NJ Diabetes Council decided to adopt the position that glycemic goals be stratified to life expectancy. Those seniors whose general medical condition and statistics indicate greater than a 10-year life expectancy should be treated by the usual adult guidelines which do not put them at undue risk of hypoglycemia. When life expectancy appears to be clinically limited, antiglycemic therapy should simply keep the patient asymptomatic, which is typically a fasting and daytime glucose variation of 125 to 225 mg/dl with hemoglobin A_{1C} of 8-9.5%. Most alert, motivated patients taking oral agents with and without insulin can attain this modest goal which will preclude rapid dehydration in the event an acute crisis intervenes.

The geriatric diabetes guidelines considered at length by the New Jersey Diabetes Council are contained in Tables 1a and 1b. The VA system also stratifies the risk of developing diabetic complications such as in the feet. This affects the frequency of clinical evaluation. These concepts are currently under review by national committees considering diabetes management, a process similar to panels that advised physicians on treating hypertension and hypercholesterolemia. Continued evolution of these ideas will occur as outcome data becomes available. In the interim, the geriatric guidelines identified by the New Jersey Diabetes Council are a measurable performance evaluation to help reduce the burden of diabetes in the state. ■

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reducing the burden of diabetes in new jersey:

A MULTIFACETED HEALTH SYSTEMS APPROACH

background

The University of Medicine and Dentistry of New Jersey (UMDNJ), Center for Continuing Education in the Health Professions (CCE), has developed a model for the integration of standards of diabetes care and patient self-management education into the policies and practices of managed care organizations (MCOs) and federally-qualified health centers (FQHCs) in New Jersey.

Diabetes is striking more Americans than ever before. According to the Centers for Disease Control and Prevention (CDC), an estimated 15.7 million Americans - nearly 6% of the U.S. population - have diabetes. Furthermore, the number of new diagnoses is averaging 798,000 per year. Diabetes has become the 7th leading cause of death in the U.S., but more than one-third of people with diabetes are unaware that they have it. The number of people with diabetes has been steadily increasing since 1980. Minorities are being hit especially hard. Among black Americans, for example, the diabetic population rose 33%, compared with 11% for white Americans. A recent General Accounting Office study has shown that although fee-for-service Medicare patients with diabetes see their physicians an average of twice a year, only 11% of these patients receive necessary preventive screening services. Data from this same study (GAO/HHS March 1997) found that Medicare patients with diabetes in New Jersey also received many fewer services than were recommended by these guidelines. Additional data from the Medicare Managed Care Quality Improvement Project showed similar utilization rates for Medicare patients with diabetes enrolled in 23 managed care plans in California, Florida, Minnesota, New York and Pennsylvania. →

THE CENTER FOR CONTINUING EDUCATION, ROBERT WOOD JOHNSON MEDICAL SCHOOL,
is pleased to announce the hiring of **PATRICIA BARTA, M.P.H., R.N., C.D.E.,** *effective December 1, 1998. Under the title "Diabetes Program Development Specialist," Pat's major responsibility is closing out a four-year grant, "Reduce the Burden of Diabetes: A Health Systems Approach."*
She can be reached at (732) 235-7430 or by e-mail at ccbarta@umdnj.edu.

Table 2

performance measures outcomes

Following is a table reflecting the guidelines for adult diabetes care with the results obtained from this pre-intervention chart audit.

BASELINE CHART KEY AUDIT FINDINGS

Overall Data Summary of Participating Agencies ■ Selected Performance Measures, Adults with Diabetes ■ One year prior to intervention in March, 1996

ADULT DIABETES PERFORMANCE MEASURES (Age > or = 18 years of age, non-pregnant)		PERCENT COMPLIANCE WITH PERFORMANCE MEASURES					
		FQHC			MCO		
		average	95% C.I.	range	average	95% C.I.	range
Frequency of visits	if meeting goals: every 6 months if not meeting goals: every 3 months, or as indicated	87%	82% – 92%	63% – 95%	91%	86% 95%	40% – 93%
Weight	every visit	77% of sample number having any recording of weight, not necessarily every visit	not available	32% – 97%	61%	not available	40% – 97%
Cardiovascular Assessment	BP every visit;	80%	75% 86%	58% – 97%	82%	76% 88%	71% – 88%
	EKG in adults, baseline and prn%	37%	29% 44%	17% – 46%	55%	48% 63%	29% – 54%
Feet Examination	check every routine visit (2 – 4 times/year) to include vascular and neuro check	39%	32% 46%	18 – 57%	33%	26% 40%	21% – 35%
Eye Examination	dilated eye exam yearly	42%	34% 49%	17% – 51%	33%	19% 33%	23% – 42%
Lipid Profile	with initial diagnosis yearly if abnormal, every 5 years if normal	chol 57% trig 64%	47% 67% not available	44% – 91% 42% – 91%	64% 33%	55% 73% not available	60% 100% 0% – 61%
Hemoglobin A_{1c}	if meeting goals: yearly, or as indicated If not meeting goals: every 3 months	42%	31% 54%	4% – 66%	32%	20% 45%	0% – 72%
Fasting or Random Blood Glucose	every diabetic visit	73%	71% 76%	37% – 100%	62%	60% 64%	43% – 62%
Creatinine	yearly	69%	62% 76%	52% – 91%	66%	59% 74%	33% – 66%
U/A for Micro Albumin	yearly	2%	<1% 4%	0% – 40%	4%	1% 7%	0% – 7%

New guidelines and clinical trial results will influence the intensity of treatment of diabetes, as well as change the epidemiology of the disease. In 1997, the ADA refined and expanded its guidelines to create two new categories: Impaired fasting glucose (IFG), when blood glucose is >110mg/dl but <126mg/dl, and impaired glucose tolerance (IGT), which is a 2-hour OGTT level >140mg/dl and <200mg/dl. The ADA recommends that every nonpregnant adult be considered for screening for diabetes at age 45, then every three years thereafter. Certain high-risk groups – American Indians, African Americans, Hispanics, and Asians — should be screened earlier and, perhaps, more frequently. Other high-risk factors include obesity, dyslipidemia, hypertension, family history, previous gestational diabetes or delivery of a baby >9 lbs at birth, and previous impaired glucose tolerance. Lastly, it was recommended that the terms, "insulin-dependent" and "non-insulin-dependent" diabetes no longer be used for type 1 and type 2 diabetes in light of the new understanding of the pathophysiology of the disease and treatment approaches.

With this background, the activities of the project are as follows:

1. To inform primary care providers (physicians, nurse practitioners, physician assistants) about performance measures for diabetes care as developed by the New Jersey Diabetes Council.
2. To provide feedback to primary care providers and participating organizations about the outcomes of medical record audits related to adherence to diabetes performance measures.
3. To provide patients with a printed tool that highlights recommended testing, examination, and intervention practices for diabetes care, and which also serves as a reminder to primary care providers about the recommendations.

A four-part intervention was developed. This intervention includes the following components: **(1)** primary care provider education; **(2)** feedback on progress toward performance measure compliance; **(3)** written reminders to be used by patients as prompts to obtain needed medical care; and **(4)** consultation by a registered nurse certified diabetes educator (CDE) to the FQHC and MCO staffs, as necessary. This grant was approved by UMDNJ in September 1996, and study sites were recruited throughout 1997. Between April 1997 and now, three newsletters, including this one, were published addressing different aspects of diabetes care and population-specific performance measures: Pediatric Performance Measures, Adult Performance Measures, Geriatric Performance Measures, and Screening/Performance Measures During Pregnancy.

METHOD (Research Design)

sampling

A pre-test, post-test design is being used to examine the effects of the Diabetes Managed Care Project. The target groups include primary care providers practicing in participating organizations and their patients diagnosed with diabetes. Based on the census estimates of the MCOs and FQHCs involved, it is anticipated that approximately 4,500 primary care providers and 8,900 persons with diabetes could be affected by the project.

A baseline medical record audit was conducted in both the FQHCs and MCOs. Since the two types of organizations are separate and distinct entities, the purpose

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1. Diabetes Control and Complications Record Group. The effects of intensive treatment of diabetes on the development and progression of long-term complications of insulin dependent diabetes mellitus., N. Engl J. Med (1993) 329:977
2. Laslo R.D. The DCCT: Implications for policy and practice (editorial), N. Engl J. Med (1993) 329:1035.

of the analysis of the data is not to make a comparison between them, but to include the outcome measures reflecting a realistically-mixed population representative of the state of New Jersey.

A sample of medical records was selected from each FQHC and the two smaller MCOs. Cluster sampling was used to select records in the largest MCO. Sufficient data are compiled to test the hypothesis that an observed increase in the sample proportions is real and not just due to random fluctuation. Approximately 400 charts were reviewed.

Identified charts fell within a one-year time frame prior to the first intervention in March 1997. The second collection of data will take place around March 1999. If necessary, more charts will be added at that time to maintain the minimum number of charts for review.

Each participating agency received an individual summary of discrete information on the collected data, as well as an overall summary, in aggregate form, of all participating agencies. The agency-specific feedback provided to individual organizations had limited statistical significance due to the small number of charts reviewed for each, but was provided to give guidance to the participating organizations in their management of patients with diabetes.

instruments

Baseline data were collected on the Adult Diabetes Performance Measures that have been defined by the New Jersey Diabetes Council. These data were obtained from the medical records using the data abstraction tool specific to the performance measures outlined by the Council. Post-intervention data will be collected and compared to baseline data to determine the degree of behavior change, if any, among primary care providers. Although all of the measures on the tool are assessed, the primary measures being analyzed include the measurement of hemoglobin A_{1c}, lipid profile, and weight.

footnote:

1. All numbers identified are being reviewed by the Director of the Office of Statistical Consulting in the Department of statistics at Rutgers University and by the statistician at the New Jersey Department of Health and Senior Services for validity and accuracy.

A report of baseline findings (pre-intervention compliance of primary care providers with adult diabetes performance measures) was developed in July, 1998. See Tables 2 and 3. Selected data from the baseline audit suggest that there is a great need to improve care, e.g., measuring, recording, and, if warranted, treating abnormal hemoglobin A1c and cholesterol levels.

summary

The baseline audit suggests that opportunities to improve the care of diabetic patients in New Jersey exist, as documented by standard performance measures. Leadership in the FQHCs, MCOs, the Department of Health and Senior Services, and the Centers for Disease Control and Prevention remain supportive of the project. It is hoped that the follow-up summary will show that these interventions have been successful. ■

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For a complete Summary of Baseline Findings from this project, please contact the Editor and Project Coordinator, Dorothy Caputo, MA, RNC, CNA, CDE.

Table 3

performance measures outcomes

continued

BASELINE CHART KEY AUDIT FINDINGS

Overall Data Summary of Participating Agencies ■ Selected Performance Measures, Adults with Diabetes ■ One year prior to intervention in March, 1996

Appropriate Referrals to Specialists		Federally Qualified Health Centers % of Patients Referred[4]			Managed Care Organizations % of Patients Referred[4]		
		average	95% C.I.	range	average	95% C.I.	range
Nutritional counseling: registered dietitian	at diagnosis and evaluate as needed	20%	14% 25%	0% – 40%	9%	5% 14%	10% – 23%
Self-management education: RN, CDE	at diagnosis and evaluate yearly	12%	7% 16%	0% 31%	7%	3% 10%	0% – 7%
Failure to obtain glycemic control: Diabetologist	fasting/ preprandial BS <80 or >140mg/dl bedtime glucose <100 or >160mg/dl $HbgA_{1C}$ >8%	4%	1% 7%	0% – 10%	12%	7% 16%	0% – 19%
Retinopathy: Ophthalmologist/ Retinal Specialist	Yearly if negative, or Acute exacerbation	45%	not available	25% – 53%	40%	not available	33% – 44%
Foot deformities, neurotropic ulcers: Podiatrist, Orthopedic or Vascular Surgeon	Acute exacerbation	29%	not available	3% – 46%	29%	not available	30% – 33%
Neuropathy: Renal Specialist	Albuminuria	1%	<1% 2%	0% – 5%	1%	<1% 3%	0% – 2%
Pregnancy: Maternal Fetal Specialist	Prepregnancy counseling: Existing diabetes Pregnancy counseling: Gestational diabetes	<1%	<1% 2%	0% – 5%	<1%	<0% <1%	0% – 2%

4 *The percentages given indicate the percent of patients referred to specific specialists. Since a determination of appropriateness of referral is beyond the scope of the reviewers, the percent of patients referred appropriately was not calculated.*

diabetes and pregnancy:

NOT JUST A PROBLEM FOR OBSTETRICIANS

Prior to the discovery of insulin in 1921, there were few pregnancies in women with diabetes mellitus. Most patients died within a few years of onset, and those who lived had impaired fertility or terribly complicated pregnancies that often ended in the stillbirth of macrosomic or malformed fetuses. Fortunately, the past seven decades have witnessed dramatic improvements in maternal and fetal outcome in pregnancies complicated by diabetes. When diabetic women receive optimal care prior to and during gestation, the perinatal mortality rate is nearly equivalent to that observed in normal pregnancies.

Despite these improvements in outcome, considerable challenges remain, particularly in the prevention of serious, life threatening and often debilitating congenital anomalies that are three to four times more common in the offspring of women with pregestational diabetes. These fetal malformations are principally caused by poor control of diabetes during fetal organ formation. This crucial time period, roughly between two and ten weeks gestation, is when most congenital malformations occur as a result of various metabolic abnormalities characteristic of poorly controlled diabetes. Thus, there has been considerable emphasis on prepregnancy counseling and early pregnancy diabetes control programs over the past ten years. Several studies in the literature have documented a significant reduction of the fetal malformation rate in women whose diabetes is tightly controlled, or who seek early specialized prenatal care during the period of organogenesis. Serious and often tragic congenital malformations such as open spina bifida, congenital heart defects, and limb malformations are in the realm of preventable disorders. This responsibility is not limited to pregnancy care providers such as obstetricians, but is equally shared by all health care professionals who care for diabetic women of reproductive age, including primary care physicians. This phenomenon presents a tremendous opportunity for preventive care. It is an unfortunate statistic, however, that only a small percentage of women with preexisting diabetes specifically seek preconception counseling or care, and thus begin their pregnancy care at a time when the window of opportunity for the prevention of serious birth defects has already passed, as early as 10 weeks gestation. Thus, it becomes extremely important for all providers of health care to diabetic women of reproductive age to be familiar with the principles of preconception care and to take the initiative to discuss these issues prior to pregnancy, and optimally assist these women in planning for pregnancy over a period of three to six months.

Diabetes mellitus is the most common medical complication of pregnancy. Approximately two to four percent of pregnancies are complicated by diabetes, though 90 percent of these cases represent gestational diabetes mellitus (GDM), which is a disorder of impaired carbohydrate metabolism of variable severity first diagnosed or recognized during pregnancy, most often in the third trimester. Some cases of GDM prove to be previously undiagnosed cases of type 2 diabetes, and post partum testing will help to identify diabetes in these individuals. GDM presents a different set of issues than preexisting diabetes, since GDM typically does not occur until the third trimester, long after fetal organ formation is complete. Pregestational diabetes is classified as type 1 or type 2, according to whether the patient requires insulin injections to avoid ketoacidosis. Patients with type 2 diabetes may require insulin for glucose regulation, but do not become ketotic if insulin is withheld.

pregestational diabetes: Preconception Counseling and Care

The greatest opportunity to prevent congenital malformations in the offspring of women with pregestational diabetes is through the provision of preconception care. This is best accomplished by a multi-disciplinary team approach which often includes a diabetologist, internist or primary care physician, obstetrician or maternal/fetal medicine subspecialist, and diabetes educators including nurses, registered dieticians, and social workers. Quite often, other specialists also need to be involved in the care of these women (nephrologists, ophthalmologists, cardiologists, etc.). This team approach before, during and after pregnancy, is necessitated by the complex nature of diabetes with issues that transcend any one specialty or discipline. Primary care physicians should carefully consider whether resources and experience for such specialized care exist in their own practice or community, or whether referral to an experienced program is the most appropriate decision. All health care providers have the opportunity, however, to at least discuss the principles of preconception care, and to begin to empower the patient to play an active role, ultimately the most important role, in the team approach to diabetes in pregnancy. Preconception care also needs to include an assessment of the patient for various vascular complications such as nephropathy, hypertension, retinopathy, cardiovascular disease, and less commonly, neuropathies.

preconception care: Specific Treatment Goals

Glycemic control during preconception care is the foundation upon which a future healthy pregnancy is built. This requires effective patient education, including appropriate dietary counseling and meal plans, and physical activity recommendations. Also necessary are education in the use of carbohydrates and glucagon for hypoglycemia, evaluation of the accuracy of self monitoring of blood glucose (SMBG), current medication review, insulin regimen review, insulin adjustment techniques, urine ketone testing and evaluation of psychosocial status including compliance issues, social support network, and stress factors related to both diabetes and pregnancy. The amount of information required by diabetic women planning pregnancy can be overwhelming, and should be supplemented with printed materials

and/or instructional videos. Comprehensive education must include an accurate assessment of the presence and stage of complications such as retinopathy, nephropathy, hypertension, atherosclerotic cardiovascular disease, and autonomic and peripheral neuropathy. Concomitant rnedical conditions and medications need to have an updated evaluation. Patients with type 1 diabetes often have associated thyroid disorders. Physical examination should include blood pressure measurements, including orthostatic changes, dilated retinal examinations by an experienced examiner, and cardiovascular examinations, including an EKG, in those with diabetes for more than 10 years or with other coronary artery disease risk factors. Extremity examination and pelvic exams, including pap smears, are also recommended. Laboratory evaluation should include (in addition to confirmation of the patient's glucose meter accuracy) glycosylated hemoglobin, assessment of renal function and thyroid function tests.

Various studies have examined the relationship between glycosylated hemoglobin levels and the risk of congenital malformations. Laboratory standards vary, but it is generally recommended to delay pregnancy until the hemoglobin A_{1C} s is below 8.0%. Hemoglobin A_{1C} s that are within the normal range for a particular lab are also acceptable. Assessment of renal function should include a serum BUN and creatinine, as well as a 24 hour specimen for total protein/albumin excretion and/or microalbuminuria. An important component of dietary counseling is a discussion of the role of folic acid in the prevention of neural tube defects. Neural tube defects, including open spina bifida and anencephaly are ten times more common in the offspring of women with pregestational diabetes, and their incidence can be reduced with folate supplementation. The author prefers 1 mg/day of folic acid, which is started when the woman is attempting pregnancy, and continued throughout gestation as a component of prenatal vitamins, though we know that neural tube closure is completed quite early in gestation.

The patient should be instructed in insulin adjustment algorithms, with the goal of achieving capillary glucose results of 70 to 100 mg/dl before meals, and post prandial values of less than 140 mg/dl one hour after meals, and less than 120 mg/dl two hours after meals. Patients should be cautioned that one of the risks of tight metabolic control prior to and early in pregnancy is hypoglycemia. Besides missed periods, hypoglycemia is often one of the first signs of pregnancy in a pregestational diabetic woman. Fasting plasma venous glucoses are normally lower than non-pregnant controls, and this is largely due to the metabolic fuel need of a growing conceptus and placenta. Patients thus need to be adequately counseled regarding corrective measures for mild, moderate, or severe hypoglycemia, including in some cases, carrying an autoinjection device containing Glucagon.

vascular complications:

Prepregnancy Counseling and Pregnancy Prognosis

Good preconception care should include an evaluation of the patient for certain vascular complications, especially in type 1 diabetes or type 2 diabetes of sufficient duration. The most common complications requiring further evaluation and counseling include diabetic nephropathy, often with concomitant hypertension, and diabetic retinopathy. Less commonly encountered are women with ischemic heart disease or renal transplant recipients. In pregnancy, diabetic nephropathy strongly influences the outcome of gestation. Maternal hazards of diabetic nephropathy include possible renal failure during or after pregnancy, superimposed preeclampsia, and the risk of eventual morbidity or mortality from vascular disease. Fetal complications include intrauterine growth restriction, stillbirth, and preterm delivery with associated neonatal disorders. Optimal outcomes for mothers and babies occur when a multi-disciplinary approach is used. With modern management, perinatal outcome has improved dramatically for women with diabetic nephropathy. Nevertheless, women with chronic renal insufficiency, especially those with serum creatinines of 3 mg/dl or higher, or creatinine clearances less than 50 mg/minute, should be counseled to avoid pregnancy unless renal function can be stabilized by renal transplantation. Renal transplant recipients require very specialized counseling, and appropriate referral is recommended. Women with diabetic nephropathy often experience a decline in creatinine clearance during pregnancy and a predictable increase in urinary albumin excretion. Fortunately, these changes are often reversible, though some women do experience a permanent, accelerated decline in renal function during pregnancy. Careful pregnancy management with good glycemic control, as well as control of hypertension, can decrease the risk of a permanent decline in renal function. These women often have coexisting hypertension, and many of them take antihypertensive drugs prior to pregnancy. ACE inhibitors are particularly well suited to counteract the glomerular hyperfiltration which is characteristic of diabetic nephropathy. Unfortunately ACE inhibitors and Angiotensin II receptor antagonists are contraindicated in pregnancy. ACE inhibitors have adverse effects on the fetal and neonatal kidney. Decisions often need to be made on the most appropriate antihypertensive agent for the woman with pregestational diabetes who is planning a pregnancy. A wide choice of agents can be used, though none is ideal for both mother and fetus. Alpha 1 receptor blockers (prazosin) and calcium antagonists may be preferred in pregnancy because of their potential beneficial effect on the long-term course of nephropathy, but data is incomplete at this time regarding potential teratogenicity. Alpha methyldopa and beta blockers are relatively safe from a fetal viewpoint, but beta blockers should be used with caution in diabetic patients because of potential effects on glycemic control and the potential to interfere with hypoglycemia awareness. Other agents that are best avoided in diabetic women include combined alpha and beta adrenergic blockers, and most diuretics. Fortunately, the risks of pregnancy-induced progression to end-stage renal disease is quite low, and recent studies of women with diabetic nephropathy report an approximately 97% neonatal survival rate, though many of these infants are delivered prematurely due to maternal medical complications or fetal growth restriction.

Diabetic retinopathy is also important to detect or assess prior to conception. Proliferative diabetic retinopathy is known to accelerate during pregnancy, with a greater than

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two-fold risk of progression, though studies have not clearly distinguished between the effects of pregnancy and those of the sudden institution of rigorous metabolic control, which itself often leads to transient worsening of retinopathy. Progression to proliferative retinopathy, which is vision threatening during pregnancy, rarely occurs in women without any retinal disease, or those with only background changes. Proliferative retinopathy may lead to vision loss if untreated, and thus should be monitored closely and managed with photocoagulation as appropriate.

pregnancy care
for Women with Pregestational Diabetes

Women with pregestational diabetes need specialized care and are often referred to maternal/fetal medicine specialists by generalist obstetrician/gynecologists. These women need a continuum of care involving a multi disciplinary team, and also require specialized tests of fetal well being, beginning in the first trimester, and continuing throughout pregnancy. A detailed discussion of pregnancy management is beyond the scope of this article.

gestational diabetes mellitus

Gestational diabetes mellitus is defined as carbohydrate intolerance of variable severity with onset or recognition during pregnancy. Insulin may or may not be required for treatment, and the condition may persist after pregnancy, which includes the possibility that carbohydrate intolerance may have preceded pregnancy. The American College of Obstetrics and Gynecology has endorsed universal screening for GDM. Until July of 1997, the American Diabetes Association and the National Diabetes Data Group also endorsed universal screening but recently modified their recommendations as follows:

"Previous recommendations have been that screening for GDM should be done in all pregnancies. However, there are certain factors that place a woman at lower risk for the development of glucose intolerance during pregnancy, and it is not likely to be cost-effective to screen such patients. The low risk group comprises women who are less than 25 years of age and of normal body weight, have no family history (i.e. first degree relative) of diabetes, and are not members of an ethnic/racial group with a high prevalence of diabetes (e.g. Hispanic, Native American, Asian, African-American.) Pregnant women who fulfill all of these criteria need not be screened for GDM."

Pregnant women who are candidates for screening (see table 4a) and have not been identified as having diabetes before the 24th week should have a screening glucose load between the 24th and 28th week consisting of a 50 gram oral glucose, given without regard to time of the last meal or time of day. Venous plasma glucose is measured one hour later. A value of greater than or equal to 140 mg/dl is recommended as a threshold to indicate the need for a full diagnostic three hour oral glucose tolerance test (OGTT). Some authorities recommend using a cutoff of 130 mg/dl, which increases sensitivity, but at the expense of an increased false positive rate and the need to perform diagnostic three hour OGTTs in 25 percent of women who are screened. Diagnosis of GDM is based on results of the 100 gram oral glucose tolerance test. Definitive diagnosis of GDM requires that two or more of the venous plasma glucose concentrations be met or exceeded: fasting 105 mg/dl, one hour 190 mg/dl, two hour 165 mg/dl, three hour 145 mg/dl. Carpenter and Coustan modified these criteria based on studies correlating OGTT values with perinatal outcome. They recommended tighter thresholds for the three hour OGTT, and those are: fasting 95 mg/dl, one hour 180 mg/dl, two hour 155 mg/dl, and three hour 140 mg/dl. Women with two abnormal values, as defined by the more stringent criteria of Carpenter and Coustan, are at increased risk for fetal macrosomia and certain neonatal metabolic complications related to in-utero hyper-

Table 4a

GESTATIONAL DIABETES MELLITUS SCREENING RECOMMENDATIONS

UNIVERSAL TESTING ACCEPTABLE	24 – 28 weeks
HIGH RISK PREGNANCIES	
A: Prior history of: GDM, Macrosomia (BW>9lbs) Unexplained fetal anomalies	
B: Maternal History of: Hypertension, Obesity, Hydramnios Diabetes Symptoms	
C: Race/ethnicity: Native American, Hispanic, African American Asian American	First prenatal visit
LOW RISK PREGNANCIES	
Must have ALL of the following: A: Under 25 years of age with normal weight	
B: No family history of Diabetes Mellitus	
C: No a member of a high-risk racial/ ethnic group	Need not be screened
SCREENING GLUCOSE CHALLENGE TEST: 50 grams (need not be fasting) Serum glucose 1 hour later	>140 mg/dl indicates formal glucose tolerance testing with 100 grams
CONFIRMATORY GLUCOSE TOLERANCE TEST: 100 grams (3 hour OGTT)	Two elevated values exceeding thresholds indicated below:
	Fasting: 105 mg/dl
	1 hour: 190 mg/dl
	2 hour: 165 mg/dl
	3 hour: 145 mg/dl

glycemia. Patients at very high risk of GDM, such as those who had GDM in a previous pregnancy, may be screened at the time of the first visit because the likelihood of recurrent GDM is approximately 50 percent. Women with one abnormal value in the three hour OGTT, using the standard, more liberal criteria, also need to have dietary counseling and periodic glycemic control assessment, since they are also at risk of fetal complications. Patients with GDM should be tested for diabetes in the non pregnant state at the time of the postpartum checkup and annually thereafter. Classification should be in accordance with the revised diagnostic criteria defined by the American Diabetes Association in July of 1997 and categorized as either **1)** Diabetes, **2)** Impaired Fasting Glucose, **3)** Impaired Glucose Tolerance or **4)** Normoglycemia.

management of GDM **(See Table 4b)**

Women identified as having GDM based on an abnormal three hour OGTT can be treated with dietary modification alone if their fasting blood sugars are less than 105 mg/dl. This approach requires periodic assessment of glycemic control to determine whether or not insulin will be necessary. Glycemic target values are: fasting blood sugars less than 105 mg/dl (though 60-95 mg/dl is a more physiologic goal), two hour post prandial values less than 120 and one hour post prandial less than 140. Women with diet controlled GDM do not need to monitor blood sugars as frequently as women requiring insulin, and it is acceptable to monitor fasting and post prandial blood sugars once or twice per week to determine whether insulin is necessary. If the fasting value of the three hour OGTT is greater than 105 mg/dl, insulin is usually necessary to maintain adequate glycemic control after meals and to prevent fetal and neonatal complications. Untreated maternal hyperglycemia leads to fetal hyperglycemia, accelerated fetal growth with characteristic truncal obesity, and increased fat deposition in the shoulders that leads to a higher risk of birth trauma with the possibility of permanent neurologic injury. Women with GDM also have an increased incidence of preeclampsia.

Women with GDM who require insulin rarely need to be hospitalized for initial insulin therapy, but do require intensive patient education regarding insulin self-injection, self monitoring of blood glucose (SMBG), and an action plan for hypoglycemic episodes. This can be accomplished if appropriate outpatient resources are available, the patient is motivated and compliant, and she demonstrates adequate understanding of the principles of diabetes management. Physicians should resist insurance-driven mandates to provide initial insulin management for all women with GDM on an outpatient basis since it is not always appropriate or safe. Cases must be individualized with regard to the most appropriate facility in which to initiate insulin treatment of GDM.

pregnancy specific **Management Issues In GDM**

Like women with pregestational diabetes, women with GDM require modified prenatal care and often benefit from consultation or co-management with Maternal/Fetal Medicine sub-specialists. Specific recommendations regarding the role of fetal growth assessment with ultrasound, antepartum fetal surveillance tests, timing and mode of delivery, and management of associated complications are beyond the scope of this article. Recent literature has provided further rationale for metabolic normalization in all women with carbohydrate intolerance in pregnancy, whether pregestational or pregnancy induced. These studies have identified a relationship between suboptimal metabolic control during pregnancy and an increased risk of subtle neurodevelopmental deficits in early childhood. Good maternal metabolic control during pregnancy in women with diabetes may also reduce the incidence of other long-term complications in offspring, such as childhood obesity and subtle abnormalities in carbohydrate tolerance in childhood. These factors represent additional concerns beyond the traditionally recognized risks of stillbirth, fetal macrosomia, and birth trauma.

conclusion

With approximately 1.5 million women of child bearing age known to have diabetes in the United States, as well as three to four percent of all pregnancies being complicated by gestational diabetes, there is a significant need for a greater awareness of potential complications and, more importantly, preventive measures among primary care physicians. This is no longer a problem just for obstetricians and endocrinologists. The principles of preconception care should be discussed with all diabetic women of reproductive age, thereby affording a tremendous opportunity to practice preventive medicine at its finest. Studies have also demonstrated a significant economic impact of good diabetes care before conception, as well as early in pregnancy, with approximately $5 saved for every $1 spent in preconception care. Grass roots political efforts have led to legislative changes in New Jersey, ensuring that diabetes supplies such as test strips and reflectance meters are reimbursable under many health plans. This author would like to see a warning included in diabetes care supplies regarding the need for preconception control of diabetes. Only through a greater awareness of the significant positive impact that proper preconception and high risk pregnancy care can have, will it be possible to further reduce complications in women and their offspring. ■

Table 4b

GESTATIONAL DIABETES MELLITUS MANAGEMENT

NUTRITIONAL COUNSELING: REGISTERED DIETITIAN	at diagnosis
SELF-MANAGEMENT EDUCATION: RN, CDE	at diagnosis
INSULIN THERAPY INDICATED	Fasting glucose >105 mg/dl
	2 hour post prandial >120 mg/dl
REFERRAL TO MATERNAL FETAL SPECIALIST, DIABETOLOGIST	Failure to achieve glycemic goals

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test questionnaire

For each question, fill in the **one** best answer on the answer sheet (page 12).

1. The most critical time period for the induction of fetal congenital malformations in women with pregestational diabetes is:

- **a.** Prior to the missed period
- **b.** 4th, 5th, and 6th month of pregnancy
- **c.** 32 - 36 weeks gestation
- **d.** 14 - 18 weeks gestation
- **e.** 2 - 10 weeks gestation

2. The most important preconception treatment goal in women with diabetes planning pregnancy is:

- **a.** Maintenance of ideal body weight
- **b.** Normalization of blood pressure
- **c.** Stabilization of diabetic nephropathy
- **d.** Achieving optimal glucose control with normal glycosylated hemoglobin
- **e.** Prevention of hypoglycemia

3. Congenital malformations of various fetal organ systems occur with an increased frequency in women with pregestational diabetes. Which of the following types of defects can be reduced with periconceptional folic acid supplementation:

- **a.** Congenital cardiac anomalies
- **b.** Skeletal dysplasia
- **c.** Neural tube defects (spina bifida)
- **d.** Renal anomalies
- **e.** Other central nervous system malformations

4. Women with pregestational diabetes of sufficient duration may have diabetic nephropathy or hypertension. Preconception counselors should be aware of the association between which class of antihypertensives and adverse fetal renal effects:

- **a.** Beta blockers
- **b.** Thiazide diuretics
- **c.** ACE inhibitors
- **d.** Alpha blockers
- **e.** Centrally-acting sympathetic inhibitors

5. The proper test for initial gestational diabetes mellitus screening in pregnant women is:

- **a.** Two-hour post-prandial blood sugar
- **b.** Two random blood sugars
- **c.** Fasting blood sugar
- **d.** 50 gram one-hour oral glucose tolerance test
- **e.** 100 gram three-hour oral glucose tolerance test

6. Gestational diabetes mellitus increases the risk of all of the following complications in offspring **except**:

- **a.** Fetal macrosomia
- **b.** Congenital malformations
- **c.** Obesity in childhood
- **d.** Subtle neurodevelopmental deficits in childhood associated with poor metabolic control during pregnancy
- **e.** Birth trauma

7. In considering the geriatric patient with diabetes, the New Jersey Diabetes Council adopted the position that:

- **a.** All patients with diabetes should be treated with the goal of maintaining a hemoglobin A_{1c} <8%, thereby preventing microvascular complications
- **b.** Glycemic goals should be stratified to life expectancy
- **c.** All seniors, regardless of life expectancy, should be treated by the recommended adult guidelines

For additional copies of newsletter, comments and inquiries, contact **PATRICIA BARTA, MPH,** *Editor and Project Coordinator at (732) 235-7430 or e-mail: ccbarta@umdnj.edu*

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8. When the life expectancy of the geriatric patient with diabetes is thought to be less than 10 years, therapy should primarily be to:

- **a.** Keep the patient euglycemic at all times
- **b.** Prescribe at least two oral hypoglycemics to prevent diabetic ketoacidosis
- **c.** Restrict any form of aerobic exercise
- **d.** Keep the patient free of symptoms of hyper- and hypoglycemia
- **e.** Remove dietary restrictions to improve quality of life

9. Which one of the following is recommended annually for the geriatric patient with diabetes?

- **a.** Flu vaccine
- **b.** Pneumovax
- **c.** Liver function test
- **d.** Thyroid function test
- **e.** Thalium stress test

10. Which of the following groups of screening activities for diabetes complications should be performed on the geriatric patient at each regular diabetes visit?

- **a.** Dilated retinal eye exam, hemoglobin A_{1c}, creatinine
- **b.** Foot exam, weight, blood pressure
- **c.** Review of all meds, U/A for proteinuria, cognitive assessment
- **d.** EKG, hemoglobin A_{1c}, lipid profile

11. The New Jersey Diabetes Council:

1. Consists of representatives from various sectors of the professional community including managed care, public health, academia and other organizations
2. Reviews the economic impact of medical access for patients with diabetes when making their recommendations
3. Regulates the implementation of diabetes management guidelines in the practice setting for all managed care organizations

- **a.** 1 and 2
- **b.** 1 and 3
- **c.** 2 and 3

12. Diabetes management guidelines developed by the Veterans Administration Health System are based on

- **a.** Evidence-based research
- **b.** Experience-based consensus among diabetes experts
- **c.** The lowest-cost, but effective, interventions

13. The DCCT demonstrated that the microvascular complications of diabetes were reduced by 50% in participating patients with a hemoglobin A_{1c} at or below

- **a.** 4%
- **b.** 8%
- **c.** 12%
- **d.** 16%

14. If there are no other risk factors for diabetes, screening for diabetes should be considered at age 45 and repeated

- **a.** Every 3 years
- **b.** Every 5 years
- **c.** Every 10 years
- **d.** Only when person is symptomatic

15. The activities of the Diabetes Managed Care project include all of the following except:

- **a.** Primary care provider education regarding performance measures for diabetes care
- **b.** Primary care provider feedback on adherence to performance measures
- **c.** Written patient reminders to prompt them to obtain needed medical care and screening services
- **d.** Consultation to staff of participating facilities by a nurse certified diabetes educator (CDE)
- **e.** 3-year tracking of patient outcomes and level of patient satisfaction

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questionnaire answer sheet

INSTRUCTIONS:

1. Read the newsletter carefully.
2. The questions are designed to provide a useful link between each submission and your everyday practice. Read each question, choose the correct answer so that they can be compared with the correct answers that will be sent to you at a later date.
3. Type your full name, address, and Social Security number in the spaces provided.
4. Use the enclosed postage-paid envelope to return your completed test or send the completed answer sheet to:

   UMDNJ-Center for Continuing Education in the Health Professions

   30 Bergen Street-ADM C710
   Newark, NJ 07107-9816

   (973) 972-4267

   Outside (973) Area Code:
   1 (800) 227-4852
5. Your answers will be graded, and you will be advised that you have passed (or failed). An answer sheet containing all correct answers will be mailed to you. Review the parts of the newsletter addressing any questions you have missed and read the materials suggested in the listed references.
6. A minimum score of 70% correct must be obtained in order for credit (AMA PRA category 1, 1.5 credit hours) to be awarded.

MR98E003 WI98
Evaluation Number

Shade circle like this: ●
NOT like this: ⊗ ✓

1	Ⓐ	Ⓑ	Ⓒ	Ⓓ	Ⓔ	9	Ⓐ	Ⓑ	Ⓒ	Ⓓ	Ⓔ
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3	Ⓐ	Ⓑ	Ⓒ	Ⓓ	Ⓔ	11	Ⓐ	Ⓑ	Ⓒ		
4	Ⓐ	Ⓑ	Ⓒ	Ⓓ	Ⓔ	12	Ⓐ	Ⓑ	Ⓒ		
5	Ⓐ	Ⓑ	Ⓒ	Ⓓ	Ⓔ	13	Ⓐ	Ⓑ	Ⓒ	Ⓓ	
6	Ⓐ	Ⓑ	Ⓒ	Ⓓ	Ⓔ	14	Ⓐ	Ⓑ	Ⓒ	Ⓓ	
7	Ⓐ	Ⓑ	Ⓒ			15	Ⓐ	Ⓑ	Ⓒ	Ⓓ	Ⓔ
8	Ⓐ	Ⓑ	Ⓒ	Ⓓ	Ⓔ						

○ Please shade this circle if you want nursing credits.

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Was this publication balanced, free of commercial bias?

Did this activity meet the stated objectives?

What topics would you like addressed in future publications?

thank you!

objectives

Upon completion of this activity, the participant should be able to:

1. Identify the relationship between poorly controlled maternal diabetes mellitus and congenital anomalies in offspring, with an emphasis on prevention.
2. Recognize the role of non-obstetric care providers, such as primary care physicians, in the prevention of diabetes-associated maternal and fetal complications with an emphasis on the principles of preconception care and counseling.
3. Discuss universal screening for gestational diabetes mellitus in all pregnant women, while recognizing the American Diabetes Association's position regarding specific subgroups in whom screening may not be cost effective.
4. Describe the importance of preconception care and counseling in women with pregestational diabetes while emphasizing the opportunity for preventive care.
5. Identify the risk stratified guidelines for the geriatric population with diabetes based upon life expectancy, and evaluate the reasons for stratified care in this population.
6. Discuss the outcomes of the baseline findings from the UMDNJ-CCE managed care project funded by CDC through the NJDOHSS regarding participating managed care organizations and federally qualified health centers.
7. Determine areas of improvement in caring for the patient with diabetes as identified by this project.

participating organizations

Physicians Health Services (formerly First Option Health Plan), Pinnacle Health Systems, University Health Plan, CAMcare, Eric B. Chandler Health Center, Jersey City Family Health Center, Newark Community Health Center, North Hudson Community Action Health Center, Plainfield Neighborhood Health Center and VNA of Central Jersey Community Health Center.

published by

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reviewed by

This newsletter was reviewed for relevance, accuracy of content and time required for participation by Louis Amorosa, MD, Steven H. Schneider, MD, Enzo Ragucci, MD, Alicia Dougherty, RN, CDE, Elizabeth B. Congdon RN, MA, Betsy Solan RN, MPH, Dorothy Caputo, MA, RNC, CNA, CDE, Patricia Barta, MPH, RN, CDE, and the New Jersey Diabetes Council. The Diabetes Gestational and Geriatric Performance Measures were reviewed for relevance and accuracy of content by all of the above.

accreditation

UMDNJ-Center for Continuing Education in the Health Professions is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

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Approval Period: 2 years

The target audience for this enduring material are those primary care providers who manage geriatric and gestational patients with diabetes, as well as all healthcare providers who care for people with diabetes.

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